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19	Evolution Nutraceuticals, Ir		No. 2:25-cv-004				
20	Miracle,			THERMOLIFE			
21 22	V.	Plaintiff,	INTERNATIO OPPOSITION				
23 24	ThermoLife International, LLC Defendant		(Oral Argumen	nt Requested)			
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I. INTRODUCTION

Cardio Miracle brought these proceedings ostensibly for urgent, extraordinary relief. Instead, seven months later, they remain pending because Cardio Miracle canceled depositions at the last hour, injected new arguments and a new expert for the first time on reply, and then told the Court it would be "manifestly unfair" not to consider its critical new arguments. Dkt. 73 at 16. The Court agreed that Cardio Miracle's reply "undoubtedly contains newly raised arguments" but denied the PI request without prejudice for Cardio Miracle to present its supposedly essential arguments. Dkt. 78 at 3. Its Renewed Motion confirms this Court should deny a preliminary injunction for two reasons.

First, Cardio Miracle has abandoned virtually all of the arguments it claimed were so essential that excluding them would be "manifestly unfair." Cardio Miracle has instead repeated the arguments it raised seven months ago. That speaks volumes. All the while, Cardio Miracle knowingly relied on ThermoLife's stipulation—out of respect for this Court—not to resume Amazon takedowns on ThermoLife's U.S. Patent No. 8,455,531 ("'531 patent"). Cardio Miracle has repeatedly insulted ThermoLife, its CEO, and its counsel—its conduct is improper and confirms there are no grounds for injunctive relief.

Second, Cardio Miracle's arguments fail on the merits. As a threshold matter, because the injunction it seeks raises First Amendment implications, Cardio Miracle must show that ThermoLife acted in bad faith. Cardio Miracle has twice failed to address that requirement; it now provides a single, conclusory sentence. The record over the last seven months confirms ThermoLife's strong basis to assert its patent rights. ThermoLife's actions are neither objectively nor subjectively baseless. The lack of bad faith is dispositive.

Even if Cardio Miracle could show bad faith (it cannot), it also fails to establish the four preliminary injunction factors. There is no likelihood of success because Cardio Miracle's strained theory of non-infringement contradicts the law and its own products' marketing, and its invalidity arguments—which the PTO already largely rejected—do not

overcome the statutory presumption of validity. There is no irreparable harm because

Cardio Miracle repeatedly delayed these proceedings to its benefit, and its own VP of

Finance admitted any alleged harm is quantifiable in dollars. The balance of hardships does

not weigh in Cardio Miracle's favor. Instead, Cardio Miracle admits Amazon represents

only 20% of its sales, and ThermoLife will suffer the irreparable harm of being forced to

compete against infringing products. Finally, the public interest does not favor an

injunction. To the contrary, it favors protecting ThermoLife's patent rights and putting a

The Court should deny Cardio Miracle's request for a preliminary injunction.

II. STATEMENT OF FACTS

stop to the unlawful sale of infringing products on Amazon.

ThermoLife previously set forth a comprehensive statement of facts. Dkt. 52 at 4-7; Dkt. 61 at 2-5; Dkt. 75 at 2-3. The facts below are most pertinent to the Renewed Motion.

The '531 patent relates to novel solid supplement formulations that offer benefits such as improved vasodilation, circulation, solubility, and dose efficiency. Dkt. 25-4 at 18:47–19:33, 24:27–25:38, 25:50–58; Dkt. 52-8 ¶ 15.

Cardio Miracle infringes claim 62 through its ongoing sales of dietary supplement products including those identified in ThermoLife's Counterclaims ("Accused Products"). Dkt. 25. That infringement was clear even before these proceedings based on scientific testing by Eurofins, a third-party laboratory, and Cardio Miracle's own product materials. Dkts. 52-18; 52-6 at 18–19. The Accused Products are "a solid supplement formulation" with 369 ppm of inorganic nitrate anion (i.e., the claimed "at least one non-ester nitrate compound"). Dkts. 52-8 ¶ 29–30; 25-6; 25-9; 52-28 at 49:21–50:3. The Accused Products' labels state they contain Agmatine, Ornithine, Citrulline, and Cysteine (i.e., the claimed "at least one isolated amino acid compound"). Dkts. 25 at ¶ 38-39; 25-6; 52-8 ¶ 39; 52-28 at 81:10–82:21. Each isolated amino acid compound is a "separate compound than the at least one non-ester nitrate." Dkts. 25-6; 52-8 ¶ 38, 29–39.

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These proceedings, which have now lasted over seven months, yielded evidence that confirms infringement. Contrary to its "disclaimer" non-infringement theory here, Cardio Miracle and its declarants have admitted that "claim 62 emerged from the reexamination with no [nitrate] quantity limitation." Dkts. 20 at 20; 52-28 at 159:19-167:25 (Cardio Miracle's Director of Nutrition admitting that claim 62 does not recite "supplementary amount of nitrate"). Cardio Miracle's own testing confirms the Accused Products contain "at least one non-ester nitrate compound"—specifically, 3.95 mg of non-ester nitrates per 10 g of product. Dkt. 1-9. Cardio Miracle's Director admits Cardio Miracle "deliberately" adds (i) organic beet root, which it knows "contains nitrate," and (ii) "L-citrulline" and "Lornithine," which are "at least one isolated amino acid compound." Dkt. 52-28 at 56:10-14, 78:10-14, 80:1-4. And each "is a separate compound than the at least one non-ester nitrate compound." In stark contrast to Cardio Miracle's repeated assurances to this Court that the Accused Products contain "only de minimis amounts of nitrate," Cardio Miracle unambiguously advertises that its products are "rich in heart-healthy nitrates." Dkt. 20 at 18; Ex. A at 3. And, independently, ThermoLife's expert and Professor of Applied Physiology, Dr. Jones, details why the Accused Products infringe claim 62. Dkt. 52-8 ¶¶ 29–31, 38-39. Cardio Miracle does not rebut his opinions, let alone via an expert.

Cardio Miracle made a tactical choice to improperly delay these preliminary injunction proceedings. That delay has unduly prejudiced ThermoLife because it stipulated—out of respect for this Court and based on the parties' express agreement that the preliminary injunction briefing would be complete *by July 3, 2025*—it would not renew an Amazon takedown based on the '531 patent until this Court ruled on the preliminary injunction. Dkts. 22; 23. To bring finality to these proceedings, ThermoLife filed a motion to strike the new and untimely arguments and expert declaration in Cardio Miracle's reply. Cardio Miracle told the Court it would be "manifestly unfair" to strike its new arguments and argued ThermoLife's Opposition and Dr. Jones's opinions had "startling contradictory

impacts on ThermoLife's positions." Dkt. 73 at 1, 16. But the "startling contradiction" is that Cardio Miracle went on to *abandon* nearly all of those untimely materials despite telling the Court it would be unfair to exclude them. Those arguments are waived.

III. LEGAL STANDARDS

Because Cardio Miracle seeks to enjoin ThermoLife from enforcing its patent rights and communicating about them, "federal law *requires* a showing of bad faith" as a threshold matter. *Myco Indus., Inc. v. Blephex, LLC*, 955 F.3d 1, 10 (Fed. Cir. 2020). Reflecting these First Amendment principles, the Federal Circuit has explained that injunctions in this context are a "*rarity*" and appropriate only in "exceptional circumstances." *GP Indus., Inc. v. Eran Indus., Inc.*, 500 F.3d 1369, 1373–74 (Fed. Cir. 2007).

In addition, Cardio Miracle must make a "clear showing" of four factors to obtain the "extraordinary remedy" of a preliminary injunction: (1) it is "likely to succeed on the merits," (2) it is "likely to suffer irreparable harm in the absence of preliminary relief," (3) the "balance of equities tips in [its] favor," and (4) an "injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc*, 555 U.S. 7, 20–22 (2008).

IV. ARGUMENT

A. Cardio Miracle's Continued Failure To Address The Threshold "Bad Faith" Requirement Is Dispositive

In its original motion Cardio Miracle did not address the threshold "bad faith" requirement. Dkts. 20; 52 at 8-11 (explaining why that is dispositive). Here, Cardio Miracle again fails to meet its burden. It provides a single conclusory sentence: "Cardio Miracle maintains that ThermoLife's Amazon takedown applications and counterclaims were filed in bad faith as ThermoLife must know that its asserted claims cannot be valid and infringed by products with de minimums [sic] amounts of nitrate." Dkt. 83 at 7. There is no argument

¹ All emphases added and internal citations and quotations omitted unless otherwise noted.

² Ninth Circuit law applies to the preliminary injunction factors; Federal Circuit law applies to patent-specific issues, including enjoining a patent owner's speech. *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894 (Fed. Cir. 1998).

or evidence in support. To the contrary, Cardio Miracle dismisses bad faith as "not relevant to counts one and two for non-infringement and invalidity." *Id.* Cardio Miracle is wrong; it is "*required*" to make a "showing of bad faith *before* a patentee can be enjoined from communicating his patent rights." *Myco*, 955 F.3d at 10.

1. ThermoLife's Actions Are Not Objectively Baseless

"Although bad faith in this context has both objective and subjective elements, the former is a *threshold requirement*." *Lite-Netics, LLC. v. Nu Tsai Cap. LLC*, 60 F.4th 1335, 1343 (Fed. Cir. 2023). A "plaintiff claiming that a patent holder has engaged in wrongful conduct by asserting claims of patent infringement must establish that the claims of infringement were objectively baseless." *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 362 F.3d 1367, 1377 (Fed. Cir. 2004). Infringement allegations are objectively baseless only if "no reasonable litigant could realistically expect success on the merits." *Lite-Netics*, 60 F.4th at 1343.

Cardio Miracle cannot show objective baselessness for three reasons. *First*, Cardio Miracle's egregious conduct confirms ThermoLife has meritorious positions. Cardio Miracle told the Court it should be able to raise a host of new non-infringement arguments on reply. But it abandoned them in the Renewed Motion, presenting only the single non-infringement contention that was in its original motion—namely, that the Accused Products do "not include a 'supplementary amount' of nitrates." Dkt. 83 at 9. Cardio Miracle is wrong. The words "supplementary amount" do not appear in claim 62—and nothing in the intrinsic record justifies importing that limitation. *Supra* at 3; *infra* at 9-10. But even under this strained interpretation, the Accused Products infringe. In fact, Cardio Miracle says the *opposite* to its customers in its current marketing material by promoting the Accused Products as "*rich in heart-healthy nitrates*." Ex. A at 3. Cardio Miracle cannot credibly maintain that, for litigation purposes, the Accused Products lack a "supplementary amount" of nitrates because they contain only "de minimis amounts," while simultaneously telling

the public that the same products are "rich" in the quantity of "heart-healthy nitrates." Cardio Miracle's marketing materials confirm infringement and its litigation-derived position precludes any accusation that ThermoLife pursued infringement in bad faith.

Second, unlike its Complaint and original motion, Cardio Miracle no longer disputes that ThermoLife tested the Accused Products for nitrates before submitting the Amazon Takedown. Cardio Miracle in fact admits that its products contain nitrates (Dkt. 83 at 9) and that claim 62's plain language does not specify a minimum amount of nitrate. Supra at 3. That should end the inquiry because it is black letter law that "the words of a claim are generally given their ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). Instead, Cardio Miracle argues ThermoLife "disclaimed" nitrate quantities that are not "supplementary" or are less than 20-30 mg. Dkt. 83 at 8-9. That is incorrect—and in any event, Cardio Miracle's ever-shifting argument does not support bad faith.

The Federal Circuit's *Lite-Netics* decision is instructive. 60 F.4th at 1347–1379. There, the accused infringer sought a preliminary injunction based on a non-infringement position that relied on a similar claim construction argument as Cardio Miracle's (called "prosecution history estoppel"). *Id.* at 1347. The Federal Circuit rejected its argument, explaining that "at this stage of the litigation (before, e.g., full claim-construction proceedings or possible expert reports on infringement)," the accused infringer failed to show "prosecution history estoppel [was] *so clearly applicable* that it is objectively baseless for [patentee] to assert infringement," which is "a determination at the core of the rationale for granting the preliminary injunction." *Id.* at 1344–45. And "[e]ven if a claim-construction analysis may ultimately support" its position (it does not), ThermoLife's "view is not objectively baseless." *Id.* at 1347–48; *Myco*, 955 F.3d at 10–14 (reversing injunction based on disclaimer because there was no bad faith). The same result follows here. Cardio Miracle cannot show that its "disclaimer" theory is "so clearly applicable that it is

objectively baseless for [ThermoLife] to assert infringement." *Lite-Netics*, 60 F.4th at 1347.

Third, Cardio Miracle does not attempt to show that ThermoLife's belief in the validity of its patent is objectively baseless. "If a district court weighing a motion to enjoin a patentee from communicating its rights determines the patent in question is not necessarily invalid or unenforceable, the objective baselessness requirement is not met, and no injunction should issue." Judkins v. HT Window Fashion Corp., 529 F.3d 1334, 1339 (Fed. Cir. 2008). Even beyond the statutory presumption of validity, the PTO has scrutinized claim 62 after issuance in reexamination and confirmed its validity. Dkts. 25-5; 25-6. Claim 62 has also withstood summary judgment and other district court challenges against prior art similar to Cardio Miracle's here. ThermoLife Int'l, LLC. v. Hi-Tech Pharms., Inc. ("Hi-Tech"), No. 15-cv-00892, Dkts. 383, 464, 474 (N.D. Ga. Aug. 4, 2023). ThermoLife's belief in the validity of its patent is well-founded. Judkins, 529 F.3d at 1339.

2. ThermoLife's Actions Are Not Subjectively Baseless

Because Cardio Miracle has twice now failed to address "objective baselessness," the Court need not reach "subjective bad faith." *Lite Netics*, 60 F.4th at 1344 ("Subjective bad faith must be addressed if allegations are determined to be objectively baseless, but not otherwise."). In any event, Cardio Miracle is silent on subjective bad faith; it never shows that ThermoLife believed its infringement assertions to Amazon were baseless. Nor could it. The record here confirms the Accused Products infringe and that ThermoLife's communications to Amazon were not in bad faith. *Supra* at 2-3. Cardio Miracle's failure to show bad faith "alone warrants" denial of an injunction. *Myco*, 955 F.3d at 10 (enjoining patentee's speech without finding of bad faith was abuse of discretion); *GP Indus.*, 500 F.3d at 1373–74; *Lite-Netics*, 60 F.4th at 1343.

B. Cardio Miracle Fails To Show The Winter Factors Are Met

Because Cardio Miracle failed to establish bad faith, the Court need not reach the four preliminary injunction factors. Still, Cardio Miracle fails to meet that burden.

1. No Likelihood Of Success On The Merits

"The burden is always on the movant to show that it is likely to succeed on the merits." *BlephEx, LLC v. Mycon Indus., Inc.*, 24 F.4th 1391, 1398 (Fed. Cir. 2022). Cardio Miracle "is required to show likelihood of success on the merits that its products do not infringe the ['531] patent or that the ['531] patent is invalid." *NOSSK, Inc. v. Fitness Anywhere LLC*, No. 21-cv-08914-BLF, 2022 WL 1093662, at *4 (N.D. Cal. Apr. 12, 2022).

No likelihood of success on non-infringement. Cardio Miracle told the Court it was critical that it raise a new non-infringement argument on reply—and yet now advances the single non-infringement argument it originally made: the Accused Products do not have "a 'supplementary amount' or more than 20-30 mg of nitrates." Dkt. 83 at 8. But Cardio Miracle concedes claim 62 lacks any express nitrate limitation. *Supra* at 3. Rather, Cardio Miracle's theory is that ThermoLife "disclaimed" the full scope of claim 62 by adding a silent requirement to the claim. *Id.* Cardio Miracle is wrong.

Cardio Miracle "bears the burden of proving the existence of a *clear and unmistakable* disclaimer that would have been evident to one skilled in the art." *Massachusetts Inst. of Tech. v. Shire Pharms., Inc.*, 839 F.3d 1111, 1120 (Fed. Cir. 2016). That is a "high burden," especially at the preliminary injunction stage. *Lite-Netics*, 60 F.4th at 1344–45; *Image Processing Techs. LLC v. LG Elecs. Inc.*, No. 2023-2136, 2025 WL 323779, at *5 (Fed. Cir. Jan. 29, 2025).

NOSSK is instructive. 2022 WL 1093662, at *1–7. As here, the accused infringer sought to enjoin the patent owner from filing Amazon takedowns. *Id.* at *1. The accused infringer acknowledged its product had a single-strap, but argued the patentee had "disclaimed" a single-strap embodiment in statements to the PTO, thereby narrowing the claim. The court disagreed, finding that "at this preliminary stage, without the aid of claim

³ Cardio Miracle is wrong that "ThermoLife has the burden of proving infringement." Dkt. 83 at 9. ThermoLife has the ultimate burden of proving infringement at trial; at this stage, the burden is on Cardio Miracle. *Id*.

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construction or expert discovery, the [c]ourt has insufficient evidence to make a determination" on disclaimer, especially where the examiner's statements indicated the patentee had not disclaimed the use of a single strap. *Id.* at *6–7.

The same result follows here. Cardio Miracle cites three statements from the 2020 reexamination (that upheld the validity of the claim) to support its "disclaimer" argument. Dkt. 83 at 8. None limits claim 62. First, Cardio Miracle relies on statements made by ThermoLife to overcome the Re-Examiner's initial rejection of claim 62 over two references—"Harris" and "Yoshimura"—which allegedly disclosed 0.02 mg and 0.1 mg of nitrates, respectively. Id. ThermoLife argued that those quantities were insufficient to disclose the "non-ester nitrate limitation" and invalidate claim 62. Dkt. 1-6 at 30; id. at 9 (describing the 0.02 mg of nitrates in Harris as not a "supplement formulation"); id. at 11-12 (similar); Dkt. 52-8 ¶¶ 32-36. But the Re-Examiner rejected, and ThermoLife abandoned, that argument. That is a critical fact that Cardio Miracle never addresses.

"[W]here an applicant abandons its unsuccessful argument, we conclude that the prosecution history lacks the clarity necessary to establish prosecution disclaimer." Malvern Panalytical Inc. v. TA Instruments-Waters LLC, 85 F.4th, 1365, 1376 (Fed. Cir. 2023). Here, the Re-Examiner rejected ThermoLife's argument regarding the 0.1 and 0.02 mg of nitrate in Harris and Yoshimura as "not persuasive because [ThermoLife] is arguing limitations that are **not** in the claims. The claims do not specify how much nitrate compound or amino acid are in the composition." Dkt. 52-20 at 7; Dkt. 52-8 ¶ 35. ThermoLife then abandoned that argument, and amended claim 62 to remove certain amino acids allegedly disclosed by Harris and Yoshimura. Dkt. 52-21 at 34 (noting removal of creatine to overcome Harris); *Id.* at 36–37 (noting removal of glutamine, isoleucine, leucine, and valine to overcome Yoshimura); Dkt. 52-8 ¶ 35. On that basis, the Re-Examiner allowed claim 62 because it was "amended to exclude prior art compositions" (i.e., certain amino acids). Dkts. 52-21 at 7; 52-8 ¶ 35. There is no "prosecution disclaimer where an

applicant made an allegedly disclaiming argument to overcome prior art, the examiner disagreed, and the applicant never repeated the allegedly disclaiming statements and instead offered alternative reasons to overcome the prior art." *Malvern*, 85 F.4th at 1376.

Second, Cardio Miracle contends that ThermoLife's expert, Dr. Lundberg, argued "that a supplementary or effective amount of nitrate would need to be more than is present in a single meal, or more than 20-30 mg or [sic] nitrate." Dkt. 83 at 8. Not so. As an initial matter, the terms "supplementary" and "effective amount" are not in claim 62, so this argument is misplaced. Moreover, Dr. Lundberg did not state that claim 62 (or any other claim) requires more than 20–30 mg of nitrate. Rather, he stated only that in the 2006-2007 timeframe, he "and other nitrate researchers expected that any effect of nitrate administration ... would require amounts of nitrate that are over ... 20-30 mg of nitrate," and thus, that ThermoLife's invention—which taught that the combination of nitrates and amino acids would have a synergistic effect—was unexpected. Dkt. 1-7 ¶ 6. That is irrelevant to whether claim 62 requires a minimum nitrate amount.

Cardio Miracle also argues Dr. Lundberg said the background amount of nitrate entering the body from saliva is 6-12 mg, which implies claim 62 requires more than that amount. Dkt. 83 at 8. That is inaccurate. Dr. Lundberg stated that "it seems unlikely that adding another 0.1 mg of nitrate on top of" the nitrate "from intake of lettuce or beetroot" and the "6-12 mg nitrate" from saliva will "produce any biologically meaningful effect." Dkts. 1-7 ¶ 8; 52-8 ¶ 34. Neither ThermoLife nor Dr. Lundberg said that 10 mg or 20–30 mg is the floor for a "supplementary" or "effective" dose of nitrate, let alone for claim 62. Statements that are, at most, "ambiguous or amenable to multiple reasonable interpretations" are not disclaimers. *Shire*, 839 F.3d at 1119.

Cardio Miracle's non-infringement argument fails for three additional reasons. *First*, even under Cardio Miracle's (incorrect) assertion that claim 62 requires "a 'supplementary amount,'" the Accused Products still infringe. Dkt. 83 at 8. As explained

above, Cardio Miracle advertises that the Accused Products are "rich in heart-healthy nitrates." Ex. A at 3. That is, Cardio Miracle tells its customers that the Accused Products contain a "rich" quantity of nitrates that provides "heart-healthy" or cardiovascular benefits. That confirms a "supplementary amount" of nitrates. **Second**, as Dr. Jones details, Cardio Miracle's own testing shows 3.95 mg of nitrates per 10 g of product (i.e., 0.395 mg of nitrates per gram of product). Dkt. 52-8 \P 31. Thus, Cardio Miracle's Accused Product (which weighs 947.5 grams) contains approximately 374 mg of nitrates (i.e., 0.395 mg nitrate/g x 947.5 g = 374 mg of nitrate). *Id.* That is indisputably a "supplementary amount" and certainly more than 20-30 mg. *Id.* Cardio Miracle never rebuts this calculation.

Third, Cardio Miracle's argument violates the doctrine of claim differentiation. "[I]t is presumed that different words used in different claims result in a difference in meaning and scope for each of the claims." Clearstream Wastewater Systems, Inc. v. Hydro-Action, Inc., 206 F.3d 1440, 1446 (Fed. Cir. 2000). Here, when ThermoLife intends to specify the amount of nitrate, the claim language says so. For instance, claim 1 of the '531 patent requires "30.7 mg nitrate ion," and claim 8 requires a "pharmaceutically effective amount of at least one nitrate salt compound." Dkt. 25-6 at claims 1 and 8.4 "[I]f [ThermoLife] intended to restrict [claim 62] to require" a specific nitrate content, "it could have included that same limitation" as in claims 1 or 8, but it did not. Unwired Planet, LLC v. Apple Inc., 829 F.3d 1353, 1358–59 (Fed. Cir. 2016); Myco, 955 F.3d at 14 (reversing preliminary injunction where movant's argument "violate[d] the doctrine of claim differentiation").

<u>No likelihood of success on invalidity.</u> Cardio Miracle abandons many of the arguments it raised in its reply and advances the same defective prior art invalidity arguments it raised in its original PI motion. The '531 patent "enjoys the same presumption

⁴ The PTO found *different claims* (including claims 1 and 8) to be patentable because they "now require minimum amounts of nitrate ion ... or require that the compositions contains an amount of nitrate sufficient to provide the stated physiological effect." Dkt. 52-22 at 7; Dkt. 52-8 ¶ 35. Importantly, the PTO did *not* make that statement about claim 62. *Id*.

of validity during preliminary injunction proceedings as at other stages of litigation." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). Cardio Miracle cannot show it is likely to overcome that presumption.

No Anticipation Under 35 U.S.C. § 102. Anticipation requires that a single prior art reference discloses every claimed element, explicitly or inherently. *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1364 (Fed. Cir. 2008). Courts routinely reject conclusory invalidity arguments unsupported by expert analysis, like Cardio Miracle's. *EZ-Ink, Inc. v. Brother Indus., Ltd.*, No. 2:21-cv-564, 2021 WL 7909312, at *4 (E.D. Va. Dec. 8, 2021).

Cardio Miracle cites Yoshimura, Harris, Miladinov, and Giampapa as alleged "prior art references that disclose dietary supplements containing the amino acids recited in claim 62 of the '531 Patent, along with various compounds that contain nitrates, including thiamine mononitrate." Dkt. 83 at 10. Not so. As to Yoshimura and Harris, the PTO rigorously considered those references' alleged disclosure of certain amino acids and thiamine mononitrate during the 2020 reexamination *and confirmed claim 62's patentability over both references*. Dkts. 52-22 at 7; 52-8 ¶¶ 35-36. Cardio Miracle identifies no errors or gaps in the Re-Examiner's findings. As to Miladinov and Giampapa, Cardio Miracle provides no pin cites or claim charts showing how those references disclose the specific claimed combination. *See* Dkt. 52-8 ¶¶ 44–55; *NOSSK*, 2022 WL 1093662, at *8 (no likelihood of success on invalidity where alleged infringer "failed to provide claim charts, annotated diagrams, or any other evidence" linking claims to prior art). Nor could it. As Dr. Jones explains, Miladinov discloses formulations with significant levels of oil, meaning it does not disclose a "solid supplement formulation" as required by claim 62. Dkt. 52-8 ¶ 46. And Giampapa does not disclose nitrates at all. *Id.* ¶ 47.

No Invalidity Under 35 U.S.C. § 101. Patent eligibility is assessed in a two-step framework: at step one, the court asks whether the claim is "directed to" a law of nature, natural phenomenon, or abstract idea; if not, the analysis ends. Rapid Litig. Mgmt. Ltd. v.

CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012). If so, the court proceeds to step two, asking whether the additional elements, alone and in combination, transform the claim into a patent-eligible application. Id. Claim 62 passes under both steps.

Cardio Miracle argues that "[w]ithout an effective or 'supplementary amount' of nitrates, the '531 patent would not possess markedly different characteristics from amino acids and nitrates found in nature." Dkt. 83 at 11. That is inaccurate and the wrong test. The Section 101 inquiry is whether the claimed subject matter—the formulation as a whole—reflects "a product of human ingenuity having a distinctive name, character [and] use ... with markedly different characteristics from any found in nature." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013). Cardio Miracle has not shown any composition in nature that includes a "non-ester nitrate" and "isolated amino acids compounds," each as "a separate compound." Dkt. 52-8 ¶ 30—42. Because claim 62 recites a new and useful composition of matter not found in nature, the § 101 inquiry ends at step one. *Thales Visionix Inc. v. U.S.*, 850 F.3d 1343, 1349 (Fed. Cir. 2017).

If the Court reaches step two, Cardio Miracle argues claim 62 "would not possess markedly different characteristics from amino acids and nitrates found in nature," "may" fail the utility and enablement requirements, and would be ineffective as a supplement. Dkt. 83 at 11. That fails for two reasons. *First*, Cardio Miracle presents no analysis or evidence, in stark contrast to *ChromaDex Inc. v. Elysium Health Inc.*, which it misreads. 59 F.4th 1280 (Fed. Cir. 2023). There, the court found that each element of the claims reads on milk. *Id.* at 1283. Here, Cardio Miracle has identified no naturally occurring formulation that meets each element of claim 62. Further, in *ChromaDex*, the "markedly different characteristics" determination was based on a comparison to the claimed composition, not its individual constituents as Cardio Miracle asserts. *Id.* at 1284. *Second*, the '531 patent teaches that the claimed formulation has utility and markedly different characteristics—the

combination of ingredients achieves synergistic effects beyond the properties of the individual components. Dkt. 25-4 at 26:63–27:2; Dkt. 52-8 ¶ 15.

Claim 62 Includes a Proper Markush Group.⁵ Cardio Miracle argues that claim 62 is invalid "due to an improper Markush group" because "the alternatives (amino acids) are not members of the claimed group (amino acid compounds)." Dkt. 83 at 12. Not so. That argument is based on the premise that an amino acid cannot be an "amino acid compound." But the '531 patent explicitly states that "amino acids" are compounds. For example, it states: "Compounds containing both a carboxyl group and an amino group are typically known as Amino Acids." Dkt. 25-4 at 2:59-60. The '531 patent further states that a "Compound" can be "a chemical substance comprising two or more different chemically bonded chemical constituent elements or ingredients." Id. at 6:45–67. And Cardio Miracle admits that an "amino acid" is "a compound with an α-amino group (-NH₂), a carboxyl group (-COOH)," i.e., two different chemically bonded constituent elements. Dkt. 57 at 3.

2. No Irreparable Harm

Cardio Miracle again fails to establish irreparable harm from the Amazon takedown (or any other action by ThermoLife). Originally, Cardio Miracle alleged it suffered reputational harm, loss of goodwill, and lost sales, but presented only (alleged) evidence of lost sales. Dkt. 20 at 26-27. ThermoLife highlighted this failure of proof in its Opposition and explained that the alleged lost sales were quantifiable and did not constitute irreparable harm. Dkt. 52 at 23-27. In its Renewed Motion, Cardio Miracle's entire irreparable harm argument is a single sentence: "While Cardio Miracle's lost sales have been substantial, ThermoLife's takedowns have compromised Cardio Miracle's standing, status, and goodwill which is irreparable with money damages." Dkt. 83 at 12-13.

The only "evidence" Cardio Miracle cites—allegations in its complaint and a

⁵ A "Markush group" claim limitation includes a list of alternatively useable members (e.g., "a material selected from the group consisting of A, B, and C."). Ex. B (M.P.E.P. § 2117).

declaration from Bruce Haglund, the VP of Finance, who merely repeats those allegations. *Shenzhen Laiderui Lighting Technology Co. Ltd. v. Zhang,* No. 2:24-cv-562, 2024 WL 22520116, at *2 (W.D. Wash. May 17, 2024) (finding "few conclusory statements in a declaration" insufficient to show irreparable harm to goodwill and reputation).

Mr. Haglund has made such "conclusory, uncorroborated" statements before. He did so in proceedings that led to his criminal conviction for financial fraud. *S.E.C. v. Wilde*, 2012 WL 6621747, at *11 (C.D. Cal. Dec. 17, 2012) (finding Haglund "acted egregiously and with a high degree of scienter in aiding and abetting a non-existent, fraudulent prime bank investment scheme"). Indeed, much of his declaration here was lifted from a different declarant in another case, belying his testimony that he drafted it "from scratch." Dkts. 52-4; 52-5; and 52-29 at 37:4-21. His statements should be given no weight.

While "[e]vidence of loss of control over business reputation and damage to goodwill [can] constitute irreparable harm," "concrete evidence in the record" is required. *Adidas Am., Inc. v. Skechers USA, Inc.*, 890 F.3d 747, 757 (9th Cir. 2018) (alteration in original). Cardio Miracle offers no concrete evidence. It identifies no customer who is even aware of ThermoLife's infringement assertions, much less reluctant to do business as a result. It submits no customer affidavits, no data showing lasting loss of market share, and no proof of reputational injury. Indeed, its VP of finance "quantifie[d] the harm in dollar terms that Cardio Miracle believes it has experienced due to Amazon's delisting of the accused products." Dkt. 52-29 at 19:16–20, 58:1–12. Cardio Miracle cannot sustain its burden. *Zhang*, 2024 WL 22520116, at *2; *EZ-Ink*, 2021 WL 7909312, at *10.

Cardio Miracle cites *John B. Hull, Inc. v. Waterbury Petroleum Prods., Inc.* for the notion that an "inability to supply customers threatens 'reputation' as a 'dependable distributor.'" 588 F.2d 24, 29 (2d Cir. 1978); Dkt. 83 at 12. But *Hull* involved a plaintiff "*deprived totally*" of the opportunity to sell its products. 588 F.2d at 29. Here, Amazon makes up *only 20*% of Accused Products' sales, so even if Amazon removed them, Cardio

Miracle could still make the vast majority of its sales elsewhere. Dkt. 20-4 \P 8.

Cardio Miracle's reliance on *Medcursor Inc. v. Shenzen KLM Internet Trad'g Co.*, 543 F. Supp. 3d 866 (C.D. Cal. 2021) is misplaced. Dkt. 83 at 13. *Medcursor* underscores why Cardio Miracle's showing is inadequate. There, the court initially denied a TRO for lack of evidence of harm (*id.* at 877) and found irreparable harm only after the plaintiff submitted concrete proof that (i) it "sells its products *almost exclusively* on Amazon" and the notice would "effectively put [it] out of business," and (ii) it had lost "first-page status" on Amazon (*id.* at 878–79). Here, the opposite is true. Cardio Miracle does not sell "almost exclusively on Amazon," and after six months of discovery presents no evidence of lost "first-page status," reputational harm, or loss of goodwill.

3. The Balance Of Equities Weighs In ThermoLife's Favor

The equities cut against Cardio Miracle given its conduct here. Cardio Miracle claimed an "urgent" need for relief. But after securing ThermoLife's agreement not to request Amazon takedowns until resolution of its original PI request—on the understanding that briefing would be completed by July 3—it delayed at every turn, including ultimately abandoning the very arguments it told the Court would be "manifestly unfair" to strike. Those choices reflect gamesmanship and weigh against extraordinary injunctive relief.

Cardio Miracle argues that removing its "products from Amazon causes irreparable harm," while "ThermoLife stands to gain only a royalty." Dkt. 83 at 13. Not so. ThermoLife has invested substantial resources in developing, patenting, and commercializing its technology, which it licenses to the supplement industry and enforces its patents against unauthorized use. An injunction barring enforcement of the '531 patent against Cardio Miracle harms ThermoLife's reputation and undermines its relationships with its licensees. *Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013) ("Where two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products

that incorporate and infringe its own patented inventions."); *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1156 (Fed. Cir. 2011).

Cardio Miracle's "status quo" argument is similarly unavailing. Dkt. 83 at 13. The Court should not "allow [Cardio Miracle] to continue infringing conduct merely because it was doing so before the legal action." *EZ-Ink*, 2021 WL 7909312, at *5. "If [the accused infringer] has allowed itself to become excessively dependent upon infringing sales, the status quo catchword does not necessarily allow it to continue such dependence." *Atlas Powder*, 773 F.2d at 1232. The same applies here.

4. A Preliminary Injunction Is Not In The Public Interest

"[A]n order preventing [ThermoLife] from enforcing a presumptively valid patent, serves no public purpose." *Marcala, LLC v. RVLock & Co., LLC*, 2024 WL 3252891, at *2 (M.D. Fla. July 1, 2024). Patents are "affected with a public interest" and exist to "promot[e] the Progress of Science and useful Arts." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). Therefore, "the public interest favors protecting patent rights." *Power Probe Grp., Inc. v. Innova Elecs. Corp.*, No. 2024-1166, 2025 WL 798861, at *3 (Fed. Cir. Mar. 13, 2025).

Allowing Cardio Miracle to continue selling its infringing products on Amazon disserves the public interest. The Accused Products are not "essential life-saving" goods (*id.*), and Amazon accounts for just 20% of Cardio Miracle's sales, so customers can buy its products elsewhere (subject to any litigation or other outcomes). Further, ThermoLife's licensees also sell on Amazon, so the public can still benefit from the patented invention.

V. CONCLUSION

ThermoLife respectfully requests that the Court deny Cardio Miracle's Motion.

The Court permitted Cardio Miracle to re-file its motion with the benefit of a complete record. ThermoLife has rebutted the arguments in the Renewed Motion. Cardio Miracle should not be permitted to again raise new or abandoned arguments on reply.

I	Case 2:25-cv-00461-DJH	Document 84 Filed 12/05/25 Page 23 of 24			
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CERTIFICATE OF SERVICE

I hereby certify that on December 5, 2025, a copy of the foregoing was filed electronically using the Clerk of Court's CM/ECF system, which will provide notice to all counsel of record.

/s/ Gregory K. Sobolski Gregory K. Sobolski